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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,025

11/20/2006

Stephen Behr

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EXAMINER

MI, QIUWEN

ART UNIT

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1655

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,025	<b>Applicant(s)</b> BEHR ET AL.	
	<b>Examiner</b> QIUWEN MI	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26 and 30-58 is/are pending in the application.
- 4a) Of the above claim(s) 34 and 36-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26, 30-33, 35 and 45-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/26/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/12/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Applicant's amendment in the reply filed on 5/9/08 is acknowledged, with the additional newly added Claims 54-58. Claims 1-25, and 27-29 are cancelled. Claims 26, and 30-58 are pending. Claims 34, and 36-44 are withdrawn as they are directed toward a non-elected invention groups or species. **Claims 26, 30-33, 35, and 45-58 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

### Claim Rejections –35 USC § 112, 1st

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48, 49, and 53 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Skin aging or dermatological conditions cannot be prevented. There is no evidence that one would not ever get skin aging by consuming the claimed plant extracts of *Chenopodium quinoa*. Unless Applicant can show on the record that skin aging would be completely prevented in every instance, Applicant is requested to cancel the word “preventing”.

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 5/9/2008, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Claims 48, 49, and 53 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating skin aging, does not reasonably provide enablement for preventing skin aging. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

It is a common sense that skin aging is inevitable, no matter what plant extracts are being used, the skin of a seventy year old will never look the same as the skin of a one year old. As evidenced by Gohman-Yahr (U, Clinics in Dermatology 14: 153-160, 1996), skin aging is a continuous phenomenon, and it is a result of programmed senescence and prolonged environmental injury to the skin (see the entire article). As mentioned above, the invention only provides the description treating skin aging, and no description prevent skin aging is being disclosed in the specification. It is the opinion of the Examiner, in light of inevitable chronologic skin aging, that Applicant is not enabled for preventing skin aging as instantly claimed. Considering this evidence, the skilled artisan, lacking information with regard to preventing skin aging, would necessarily need to perform tedious trial and error protocols without expectation of success in order to provide for the claimed activity.

*In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; *however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112*; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved." (Emphasis added)

Due to the large quantity of experimentation necessary to generate the infinite number of variants/fragments recited in the claims and possibly screen same for activity and the lack of guidance/direction provided in the instant specification, this is merely an invitation to the skilled artisan to use the current invention as a starting point for further experimentation. Thus, undue experimentation would be required for a skilled artisan to make and/or use the claimed invention commensurate in scope with the claims.

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Applicant cites the MPEP references *In re Cortright*, 165 F3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999), and argues “ Similarly, in the present case, Applicant asserts that a worker skilled in the art, having reference to the instant application and the state of the art, would appreciate that the term "preventing" in the context of skin ageing is intended to require only some degree of prevention, such as delaying the onset of skin ageing, retarding the appearance of one or more of the effects of skin ageing, slowing the progression of one or more effects of skin ageing, and the like, rather than complete prevention, as suggested by the Examiner” (page 8, 2<sup>nd</sup> paragraph from the bottom).

This is not found persuasive. “Preventing skin aging” are totally different from delaying the onset of skin ageing, retarding the appearance of one or more of the effects of skin ageing, or slowing the progression of one or more effects of skin ageing. Unless Applicant can show on the record that skin aging would be completely prevented in every instance, Applicant is requested to cancel the word “preventing”.

Applicant argues that “The Registry contains numerous examples of issued patents claiming methods or compositions for preventing skin ageing or dermatological changes in the skin” (page 8, last paragraph).

It is not the Examiner’s position to make comment on other issued patents, or look into whether those patents have written descriptions for their claims. The purpose of this Office Action is to exam whether the current Applicant is in possession of what he/she claims.

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Applicant argues that “With respect to the Examiner's allegation that the specification, while being enabling for treating skin ageing, does not reasonably provide enablement for preventing skin ageing, Applicant respectfully disagrees. As noted above, a worker skilled in the art, having reference to the instant application and the state of the art, would appreciate that the term "preventing" in the context of skin ageing is intended to require only some degree of prevention, such as delaying the onset of skin ageing, retarding the appearance of one or more of the effects of skin ageing, slowing the progression of one or more effects of skin ageing, and the like. The present specification provides extensive teaching regarding the preparation of the plant extracts (see, for example, page 18, line 20 to page 22, line 29), testing the plant extracts for their ability to affect cellular activities in skin that are associated with skin ageing (see, for example, page 16, line 7 to page 31, line 20), and how to formulate the plant extracts for administration (see, for example, page 36, line 22 to page 46, line 5). Furthermore, the specification provides numerous Examples demonstrating the activity of various plant extracts, not only in inhibiting extracellular proteases associated with skin ageing effects (see, for example, Example II), but also in inhibiting cellular activities that lead to skin ageing (see, for example, Examples VI, XII and XIV), as well as in promoting collagen formation (see Example XI). Accordingly, the Applicant asserts that the instant specification is fully enabling not only for treating skin ageing, as noted by the Examiner, but also for preventing skin ageing)” (page 10, last paragraph; page 11, 1<sup>st</sup> paragraph).

This is not found persuasive. As stated above, “Preventing skin aging” are totally different from delaying the onset of skin ageing, retarding the appearance of one or more of the effects of skin ageing, or slowing the progression of one or more effects of skin ageing. Unless

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Applicant can show on the record that skin aging would be completely prevented in every instance, Applicant is requested to cancel the word “preventing”. Although Applicant provides a very detailed specification, Applicant failed to show evidence that one would not ever get skin aging by consuming the claimed plant extracts of *Chenopodium quinoa*.

### **Claim Rejections –35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26, 30-33, 35, and 45-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2000336024A in view of Diot (FR 2760746).

This is a new rejection necessitated by the Applicant’s amendment filed on 5/9/08.

JP 2000336024 A teaches cosmetic (dermatological) compositions containing one or more humectant plant extracts of *Chenopodium quinoa* etc for dry skin (see Abstract). JP 2000336024A teaches a sample preparation of lotion (thus topical, administering to a subject) comprising purified water (physiologically acceptable carrier), polyethylene glycol 1000 (moisturizing agent), and Quinoa (the same as *Chenopodium quinoa*, see page 4, [0008]) in 20% EtOH extract (solvent extraction) (alcoholic solvent) (see full translation, page 27, [0085]). JP 2000336024 also teaches that composition of cosmetics that contain moisture-retaining plant



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extracts with sustained moisture-retention effects over extended periods, and possess properties effective for skin treatments that prevent, alleviate, or improve such conditions as dryness, rough skin, cracks, chaps, dandruff, pruritus and inflammatory diseases (maintain and/or improve the health and/or appearance of the skin in a subject) (see page 32, [0100]). JP 2000336024 further teaches Quinoa extract in 30% PG (propylene glycol, see page 24, [0074]) in test solutions (see page 26, Table 2).

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use as inhibiting the activity of matrix metalloprotease-9 (MMP-9) or increasing collagen production. It is deemed that the composition disclosed by JP 2000336024A is not precluded for carrying out the intended function of the claims because the referenced composition comprises the one and the same ingredient disclosed by Applicant as having the claim-designated functions.

JP 2000336024 does not teach the plant material from *Chenopodium quinoa* comprises *Chenopodium quinoa* seeds.

Diot teaches a cosmetic composition comprising amino acid derivative from seeds of *Chenopodium quinoa*.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to include the seeds of *Chenopodium quinoa* in the cosmetic composition since Diot teaches a cosmetic composition comprising amino acid derivative from

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seeds of *Chenopodium quinoa*. Since both of the compositions yielded beneficial results in cosmetic industry, one of ordinary skill in the art would have been motivated to make the modifications.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant states that “Applicant respectfully directs the Examiner to pages 24-25 of the translated version of JP 2000336024A, where the ability of the *Chenopodium quinoa* plant extract to retard moisture loss from the surface of the skin is described. Applicant asserts that, contrary to the Examiner's suggestion, JP 2000336024A demonstrates that the intrinsic mechanism/pathway for the moisturising effect of the described *Chenopodium quinoa* plant extract is in fact through its ability to act effectively as a "barrier" thereby retaining moisture in the epidermal, or surface, layer of the skin. In contrast, matrix metalloproteases, including MMP-9, exert their activity at the cellular level, in particular within the extracellular matrix (ECM), which is also the location of the skin structural component, collagen (see, for example, page 2, lines 1-11, of the instant application). Applicant asserts that, as such, the skilled worker would not consider either MMP-9 activity or collagen production to play a role in preventing moisture loss from the epidermal surface. Moreover, Applicant asserts it is well-known in the art that the ability of a compound or composition to moisturise the skin is not necessarily an indication that the compound/composition inhibits MMP-9 or induces collagen production. If it were otherwise

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it could be claimed that any moisturising agent has anti-MMP-9 and collagen inducing effects, which the skilled worker would appreciate is certainly not the case. As such, Applicant asserts that the fact that a plant extract is described as having a moisturising effect on the skin in no way renders obvious its ability to inhibit MMP-9 activity or to induce collagen production” (page 13, 1<sup>st</sup> paragraph).

This is not found persuasive. As indicated above, the intended use of the composition was analyzed for patentable weight. It is deemed that the preamble ‘breathes life’ into the claims in that the prior art product must not be precluded for use as inhibiting the activity of matrix metalloprotease-9 (MMP-9) or increasing collagen production. It is deemed that the composition disclosed by JP 2000336024A is not precluded for carrying out the intended function of the claims because the referenced composition comprises the one and the same ingredient disclosed by Applicant as having the claim-designated functions.

Applicant argues that “In the instant application, Applicant has recognized and demonstrated that *Chenopodium quinoa* plant extracts, amongst others, have unexpected additional properties, including the ability to inhibit MMP-9 activity and increase collagen production. While moisturising the skin may have an indirect effect on maturing skin through water retention, it is known in the art that skin ageing, including the formation of wrinkles, is the direct result of structural changes that are due in large part to an increase in the activity of certain matrix metalloproteases (MMPs) including MMP-9, as well as a concomitant increase in the breakdown of various components of the ECM, including collagen (see, for example, page 2, lines 10-21, and page 3, lines 10-23, of the instant application). The Applicant's recognition of

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the ability of the *Chenopodium quinoa* plant extracts to inhibit MMP-9 activity and increase collagen production and thus directly affect skin ageing phenomena through these activities, allowed the Applicant to identify additional uses for the plant extracts in ameliorating or preventing conditions associated with MMP-mediated skin structural changes including, for example, wrinkle formation or appearance, loss of skin elasticity and the like. Applicant asserts that since JP 2000336024A fails to recognize the ability of the *Chenopodium quinoa* plant extracts to inhibit MMP-9 activity and increase collagen production, the skilled worker having regard to JP 2000336024A would not have contemplated using *Chenopodium quinoa* plant extracts for uses that rely on these effects” (page 13, last paragraph; page 14, 1<sup>st</sup> paragraph).

Applicant’s argument is not found persuasive. As according to MPEP 2112.01, “Products of identical chemical composition can not have mutually exclusive properties.” A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Since the cited art uses the same material *Chenopodium quinoa* plant extract externally as claimed, it is deemed that the *Chenopodium quinoa* plant extract would inhibit the activity of extracellular protease MMP-9, and increase collagen production as instantly claimed.

Applicant argues that “JP 2000336024A does not describe *Chenopodium quinoa* seed extracts. JP 2000336024A describes at page 4, paragraph 0007 of the translated version that the preparation of the plant extracts "is performed with the leaf, stem, root, flower, seed or whole plant." The specific Examples included in JP 2000336024A, however, fail to indicate which part or parts of the *Chenopodium quinoa* plant are used to

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prepare the described extracts. Applicant asserts that the numerous plant parts and possible combinations presented by JP 2000336024A, taken together with the lack of guidance therein as to which plant parts to utilize to prepare a *Chenopodium quinoa* extract, are simply an invitation for the worker skilled in the art to experiment in order to identify a *Chenopodium quinoa* extract that has the required moisture-retaining properties.

Applicant's arguments have been fully considered and are persuasive. Therefore, the previous 102/103 rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Diot.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejection is maintained.

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### Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Michele Flood/

Primary Examiner, Art Unit 1655